

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

9977 '03 APR -4 AIO :22

Reference:
April 3, 2003
FDA Docket No. 02N-0276, Section 305 Registration of Food Facilities
Under the
Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Food trade is a major component of Chile's exports. In the case of the United States of America, Chilean food exports totaled as much as \$1,664 million dollars in 2002. This represents almost 47% of the total value of our shipments to the U.S.

Introducing, developing and maintaining the highest quality, hygiene and safety standards in the production and exportation of food have always been a national priority. It is in Chile's best interest to continue strengthening these features of our food industry, since these high standards have made our country one of the largest fruit, sea food and wine exporters of the Southern Hemisphere.

The norms proposed by the FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("*Registration of Food Facilities*" and "*Prior Notice of Imported of Food Shipments*") seek to guarantee the safety of food supply –both from domestic and imported origins— in the United States. The discussion and implementation of these regulations are a renewed opportunity for strengthening the long established and close bilateral cooperation on these issues.

The collaboration and joint activities carried out throughout the years with the U.S. Department of Agriculture, the Food and Drug Administration (Department of Health and Human Services) and the Bureau of Alcohol, Tobacco and Firearms (Department of the Treasury), have facilitated trade flows while at the same time safeguarded SPS standards and protected public health.

All this has been possible through close cooperation, amongst other activities, in:
(1) the massive preclearance program run jointly by the Animal and Plant Health Inspection Service (APHIS) of the USDA and Servicio Agrícola y Ganadero (SAG), Chile's official inspection service. This program has been in place since 1982.

02N-0276

C77

(2) numerous training programs addressed at improving different aspects of food safety and Good Agricultural Practices (GAPs) which have been jointly run by the FDA and Chile's Ministry of Agriculture and SAG; and

(3) joint activities between ATF and SAG in issues relating to labeling and commercialization of Chilean wines in the U.S. market.

Given this long established bilateral relationship addressing food safety issues, the proven effectiveness and security of the system currently in place in Chile – run in conjunction by official U.S. and Chilean agencies— as well as the fact that our country does not pose a threat to the food supply of the United States, Chile urges the FDA to provide for flexibility in the design of the norms and rules under consideration.

Chile expects that the FDA would:

(1) rely upon the proven security safeguards and registration mechanisms, the food safety systems and controls, as well as the reporting and traceback mechanisms used by the food industry in Chile; and

(2) use the reports that our producers provide to U.S. Customs in compliance with the new regulations requiring advanced notice of food exported to the United States.

General Comments:

The comments that follow below are relevant both to Section 305 ("*Registration of Food Facilities*") and to Section 307 ("*Prior Notice of Imported Food Shipments*") of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002:

(1) The distribution of legal text, supporting documents, official forms and relevant background information should be accompanied by official translations (to Spanish in the case of most Latin American countries) to facilitate comprehension and proper use.

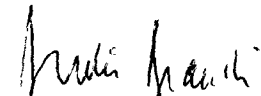
(2) Additionally, effective and timely implementation of the rules under consideration would require focused and intensive training at all levels, both of government officials, as well as firm managers, establishment supervisors and floor operators. This could be accomplished through a combination of teaching seminars and workshops for local trainers, video conferences, slide and video presentations, on-line training manuals, and explanatory leaflets focusing on specific issues like registration and prior notice forms. All this should be done in several languages and on a continuing basis until smooth implementation of new rules is achieved.

(3) The implementation period of the new rules is of particular concern to Chile's commercial interests since it overlaps with the beginning of our main fresh fruit export season. Chile intends to comply in a timely manner with the new rules once they are finally approved. Nevertheless, their implementation may prove to be a major barrier to foreign shipments due to the additional strains and demands upon communication systems, port and airport facilities, and on the inspection infrastructure. Hence, Chile urges the FDA to consider relying upon the proven security safeguards and registration mechanisms, the food safety systems and controls, as well as the reporting and traceback systems currently in place in Chile, run by official U.S. and Chilean services.

Specific Technical Comments:

Various Chilean trade associations will be submitting detailed technical comments on specific aspects of rulemaking under Section 305.

However, there is a generalized opinion that managers and plant operators need a clearer definition of the various types of establishments –as well as of their operations—that should register. This is essential in order to accomplish an effective and timely registration of all Chilean food facilities exporting to the United States.



Andrés Bianchi
Ambassador of Chile